APR - 1 2004

K040087

Submitter: Scion International Inc.
12415 SW 136 Ave. Unit 2
Miami.Fl. 33186

Contact Person: C.Kenneth French
254-435-2306
ckennethfrench@scionvalley.com

Establishment Registration Number: We are registered with the Food and Drug Administration as Establishment Number [illegible]

Date Prepared: 12-23-03

Name of Device: Common name: Biopsy Instrument
Trade name: Rabbit
Classification name: Instrument, Biopsy

Devices to which substantial equivalence is claimed:

| 510(K) # | Device | Manufacture |
|---|---|---|
| K983296 | Auto Suture ABBI System | U.S. Surgical Corporation |
| K011575 | SiteSelect Breast Biopsy Device | Imagyn Surgical |
| K003297 | Mammotome | Ethicon |

Device Description: The Candidate Device is a coaxial breast biopsy system, which is intended to retrieve tissue samples from the breast for histological analysis .The device is provided sterile for single use only. The system includes a disposable biopsy device, Localization needle, stylet, and hook wire. The biopsy device includes a circular scalpel and a Garrote wire to transect the specimen.

Rabbit
510 (k) Notification

CONFIDENTIAL

Intended use: The Rabbit is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g. malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Materials: All of the materials used to produce the Rabbit are in accordance with ISO Standard # 10993-1.

- end of summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2004

Scion International, Inc.
c/o Mr. C. Kenneth French
QA/QC
Scion Valley, Inc.
7930 Highway 22
Meridian, Texas 76665

Re: K040087
Trade/Device Name: Rabbit
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy istrument
Regulatory Class: II
Product Code: KNW
Dated: January 15, 2004
Received: January 20, 2004

Dear Mr. French:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K040087

Device Name: Rabbit

Indications For Use: The Rabbit is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K040087